

REMARKS/ARGUMENTS

The Office Action mailed March 16, 2007, has been received and reviewed. Claims 1 through 84 are currently pending in the application. Claims 21 through 27 and 49 through 83 have been withdrawn from consideration as being drawn to non-elected inventions. Claims 1 through 20, 28 through 48, and 84 stand rejected. Applicants have amended claims 2, 3, 6, 8, 9, 12, 16, 28-31, 37, 38, and 84, have cancelled claims 1, 4, 5, 7, 20, 36, and 48, and respectfully request reconsideration of the application as amended herein.

35 U.S.C. § 112 Claim Rejections

Claims 1 through 20, 28 through 48, and 84 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to “enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.” Applicants respectfully traverse this rejection, as hereinafter set forth.

Independent claims 2, 3, 28-31, and 84 have been amended to specifically recite that the polymers are lactic acid-based polymers, and to recite specific solvents. As such, applicants believe that the rejection has been overcome.

Claims 1, 3 through 20, 28 through 48, and 84 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection, as hereinafter set forth. Claims 1, 3, 28-31 and 84 have been amended to remove the term “broad” therefrom. Claims 20 and 48 have been cancelled. As such, applicants believe that the rejections have been overcome.

35 U.S.C. § 102 Anticipation Rejections

Anticipation Rejection Based on PCT International Application No. WO 02/38185 to Dunn et al.

Claims 1, 4, 7 through 9, and 12 through 20 stand rejected under 35 U.S.C. § 102(a) and (e) as being anticipated by Dunn et al. (PCT International Application No. WO 02/38185). Applicants respectfully traverse this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1, 4, and 7 have been cancelled. Claims 9 and 12-20 depend from independent claim 2, which was not found anticipated by Dunn et al. As such, applicants submit that the rejection has been overcome.

Anticipation Rejection Based on U.S. Patent No. 5,540,937 to Billot et al., as evidenced by the definition of “gel” from Answers.com

Claims 1, 4, 7 through 9, and 12 through 20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Billot et al. (U.S. Patent No. 5,540,937), as evidenced by the definition of “gel” from Answers.com. Applicants respectfully traverse this rejection, as hereinafter set forth.

Claims 1, 4, and 7 have been cancelled. Claims 9 and 12-20 depend from independent claim 2, which was not found anticipated by Dunn et al. As such, applicants submit that the rejection has been overcome.

Anticipation Rejection Based on U.S. Patent No. Application Publication No. US 2003/0027833 A1 to Cleary et al.

Claims 1, 4, 7 through 9, and 12 through 20 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Cleary et al. (U.S. Patent Application Publication No. US 2003/0027833 A1). Applicants respectfully traverse this rejection, as hereinafter set forth.

Claims 1, 4, and 7 have been cancelled. Claims 9 and 12-20 depend from independent claim 2, which was not found anticipated by Dunn et al. As such, applicants submit that the rejection has been overcome.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 5,540,937 to Billot et al. in View of PCT International Application No. WO 02/38185 to Dunn et al.

Claims 1 through 20, 28 through 48, and 84 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Billot et al. (U.S. Patent No. 5,540,937) in view of Dunn et al. (PCT International Application No. WO 02/38185). Applicants respectfully traverse this rejection, as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

The 35 U.S.C. § 103(a) obviousness rejections of claims 1-20, 28-48, and 84 are improper because the cited references do not teach all of the claim limitations.

As acknowledged by the Examiner, Dunn teaches a composition having a beneficial agent that forms a suspension therein, but does not teach or suggest that such a suspension is a gel, that the polymer and solvent form a gel, or that the beneficial agent is dissolved or dispersed with in the gel matrix. Dunn also does not teach or suggest that the composition includes low, high, and/or medium molecular weight lactic acid-based polymers, as required by the independent claims of the present application.

Billot is relied upon as teaching compositions that have a release rate of greater than 6 months, which can read on a duration of one year. (Office action at page 11).

However, the combination of Dunn and Billot do not teach or suggest all of the claim limitations, as discussed above. Moreover, Billot teaches away from forming a gel from a lactic acid-based polymer and the particular solvents recited in the pending independent claims. Instead, Billot teaches use of a solvent evaporation process to form hardened microspheres after

evaporation of the solvent is complete. Thus, a gel that includes the polymer and solvent is not taught or suggested, as the solvent is evaporated to create the microsphere. (See Billot at Abstract). As stated in Example 1, the “solvent is completely evaporated under vacuum, added again to the formed mass, and then evaporated again to form microspheres that are then harvested by filtration. (Billot at Col. 8, lines 4-16).

As such, the combination of Billot and Dunn do not teach or suggest every claim limitation and, in fact, teach away from forming a polymer and solvent gel. In view of the foregoing, Applicants respectfully request withdrawal of the present rejection.

Provisional Double Patenting Rejection Based on Copending U.S. Patent Application No. 10/701,939 (Publication No. US2004/0151753A1)

Claims 1, 4, 7 through 20, and 84 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 through 3, 5, 7, 8, 10, 17, 18, and 113 of copending U.S. Patent Application No. 10/701,939 (Publication No. US2004/0151753A1). In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants’ filing of the terminal disclaimer should not be construed as acquiescence in the Examiner’s double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

Provisional Double Patenting Rejection Based on Copending U.S. Patent Application No. 10/295,527 (Publication No. US2003/0170289A1)

Claims 1, 4, 7 through 9, and 12 through 20 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6 through 12, 15, 16, 18, and 19 of copending U.S. Patent Application No. 10/295,527 (Publication No. US2003/0170289A1). In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants’ filing of the terminal disclaimer should not be construed as acquiescence in the

Examiner's double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

Provisional Double Patenting Rejection Based on Copending U.S. Patent Application No. 10/606,969 (Publication No. US2004/0001889A1)

Claims 1, 4, 7 through 9, 12 through 20, and 84 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 through 6, 14 through 16, 18, 21, 22, 24, 27, 28, 29, 34 through 36, 38, 40 through 43, 51, 52, 57 through 59, and 105 of copending U.S. Patent Application No. 10/606,969 (Publication No. US2004/0001889A1). In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants' filing of the terminal disclaimer should not be construed as acquiescence in the Examiner's double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

Provisional Double Patenting Rejection Based on Copending U.S. Patent Application No. 11/554,540

Claims 1, 4, 7, 8, and 12 through 20 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 through 12 of copending U.S. Patent Application No. 11/554,540. In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants' filing of the terminal disclaimer should not be construed as acquiescence in the Examiner's double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

Provisional Double Patenting Rejection Based on Copending U.S. Patent Application No. 10/857,609 (Publication No. US2005/0079202A1)

Claims 1, 4, 7, 8, and 12 through 20 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 through 3, 5 through 12, and 15 through 17 of copending U.S. Patent Application No. 10/857,609 (Publication No. US2005/0079202A1). In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants' filing of the terminal disclaimer should not be construed as acquiescence in the Examiner's double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

ENTRY OF AMENDMENTS

The amendments to claims 2, 3, 6, 8, 9, 12, 16, 28-31, 37, 38, and 84 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. 1, 4, 5, 7, 20, 36, and 48

CONCLUSION

Claims 2, 3, 8-19, 28-35, 37-47, and 84 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional

issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



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Date: June 18, 2007

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